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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/010,317	01/21/1998	MAGNUS HOOK	TAMK:189	8522

7590 12/03/2001

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EXAMINER
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ZEMAN, ROBERT

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/03/2001

26

Please find below and/or attached an Office communication concerning this application or proceeding..

## Office Action Summary

**Application No.**

09/010,317

**Applicant(s)**

HOOK ET AL.

**Examiner**

Robert A Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 02 September 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 54-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5+6.                      6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-2-2001 has been entered.

All prior pending claims have been canceled. Claims 54-59 have been added. Claims 54-59 are pending and currently under examination.

### *Priority*

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971).

The instant application is drawn to methods of generating an antibody that binds to a fibronectin-binding domain of a fibronectin binding protein and inhibits binding of said fibronectin binding protein to fibronectin. Said method comprises administering to an animal or human a peptide of a

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fibronectin binding protein that **does not** bind to fibronectin. Said peptides are recited as having the amino acid sequences of SEQ ID NO:2-10, 13, 17-20, 54-61, 86-87 and 103-104. The sequences disclosed in instant application do not appear to be disclosed in application 60/036139. Consequently, in the absence of evidence to the contrary, the filing date of the instant application will be used as the priority date.

### *Specification*

The disclosure is objected to because of the following informalities: the disclosure recites incomplete ATCC accession numbers (see page 9 for example).

Additionally, SEQ ID NO:3 appears to be identical to SEQ ID NO:4 and SEQ ID NO:9 appears to be identical to SEQ ID NO:10.

Appropriate correction is required.

### *Claim Objections*

Claims 55-59 are objected to because of the following informalities: Dependent claims should begin the article "The". Appropriate correction is required.

### *Claim Rejections Withdrawn*

The rejection of claims 33-35 and 37 under 35 U.S.C. 102 (e) as being anticipated by Burnham et al. is withdrawn. Cancellation of said claims has rendered the rejection moot.

The rejection of claims 33-35 and 37 under 35 U.S.C. 102 (e) as being anticipated by Hooke et al. is withdrawn. Cancellation of said claims has rendered the rejection moot.

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*New Claim Rejections*

*35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 is rendered vague and indefinite by the use of the term “consists essentially of”. This language is unclear in the context of a polypeptide sequence. In compositions, this phrase allows the addition of other ingredients or elements that do not affect the properties of the composition. It is not possible to know what sequences can be added to the recited polypeptides that would not materially affect the nature of that polypeptide sequence.

Claims 57- 58 are rendered vague and indefinite by the use of the term “positive candidate peptide”. It is unclear what criteria, if any, other than the inability to bind fibronectin are used to determine if a given peptide is a “positive candidate”.

Claim 57 is rendered vague and indefinite by the use of the term “dispersing”. It is unclear what methodologies Applicant is claiming. As written, it is impossible to determine the metes and bounds of the claimed invention.

*35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (Infection and Immunity, Vol. 65, No. 2, 1997 pages 537-543—IDS-5).

The instant application is drawn to methods of generating an antibody that binds to a fibronectin-binding domain of a fibronectin binding protein and inhibits binding of said fibronectin binding protein to fibronectin. Said method comprises administering to an animal or human a peptide of a fibronectin binding protein that **does not** bind to fibronectin. Said peptides are recited as having the amino acid sequences of SEQ ID NO:2-10, 13, 17-20, 54-61, 86-87 and 103-104.

Sun et al. disclose peptides/proteins with the amino acid sequences of SEQ ID NO:2, 5, 7, 60 and 86-87 and methods of generating antibodies using said peptides. Sun et al. further disclose that said antibodies were capable of inhibiting fibronectin binding. Sun et al. differs from the instant invention in that they do not disclose that peptides used were unable to bind

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fibronectin. However, since the disclosed sequences are the same as those recited in the instant claims, all properties would be shared by both sets of peptides. It should also be noted that the instant claims recite “consists essentially of”. In compositions, this phrase allows the addition of other ingredients or elements that do not affect the properties of the composition. However, in the instant case it is not possible to know what sequences can be added to the recited polypeptides that would not materially affect the nature of that polypeptide sequence. Consequently the claims, in absence of evidence to the contrary, read on the entire fibronectin binding protein or any fragments thereof.

Claims 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hook et al. (WO 92/02555—IDS-5).

Hook et al. disclose peptides/proteins with the amino acid sequences of SEQ ID NO: 3, 9, 61, 87 and 104 and that said peptides could be used to generate antibodies (see page 16). Hook et al. further disclose that said antibodies were capable of inhibiting fibronectin binding. Hook et al. differs from the instant invention in that they do not explicitly disclose that peptides used were unable to bind fibronectin. However, since the disclosed sequences are the same as those recited in the instant claims, all properties would be shared by both sets of peptides. It should also be noted that the instant claims recite “consists essentially of”. In compositions, this phrase allows the addition of other ingredients or elements that do not affect the properties of the composition. However, in the instant case it is not possible to know what sequences can be added to the recited polypeptides that would not materially affect the nature of that polypeptide

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sequence. Consequently the claims, in absence of evidence to the contrary, read on the entire fibronectin binding protein or any fragments thereof.

Claims 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hook et al. (US 5,440,014—IDS-5).

Hook et al. disclose peptides/proteins with the amino acid sequences of SEQ ID NO:3, 9, 61 and 104 and that said peptides could be used to generate antibodies (see abstract). Hook et al. further disclose that said antibodies were capable of inhibiting fibronectin binding. Hook et al. et al. differs from the instant invention in that they do not explicitly disclose that peptides used were unable to bind fibronectin. However, since the disclosed sequences are the same as those recited in the instant claims, all properties would be shared by both sets of peptides. It should also be noted that the instant claims recite “consists essentially of”. In compositions, this phrase allows the addition of other ingredients or elements that do not affect the properties of the composition. However, in the instant case it is not possible to know what sequences can be added to the recited polypeptides that would not materially affect the nature of that polypeptide sequence. Consequently the claims, in absence of evidence to the contrary, read on the entire fibronectin binding protein or any fragments thereof.

Claims 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huff et al. (Journal of Biological Chemistry, Vol. 269, No. 22, 1994, pages 15563-15570—IDS-5).

Huff et al. disclose peptides/proteins with the amino acid sequences of SEQ ID NO:5, 9 and 103. Huff et al. et al. differs from the instant invention in that they do not explicitly disclose



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that peptides used were unable to bind fibronectin or that said peptides could be used to generate antibodies. However, since the disclosed sequences are the same as those recited in the instant claims, all properties would be shared by both sets of peptides. Additionally, it would have been obvious to one of the skill in the art to use said peptides to generate antibodies. Finally, it should also be noted that the instant claims recite "consists essentially of". In compositions, this phrase allows the addition of other ingredients or elements that do not affect the properties of the composition. However, in the instant case it is not possible to know what sequences can be added to the recited polypeptides that would not materially affect the nature of that polypeptide sequence. Consequently the claims, in absence of evidence to the contrary, read on the entire fibronectin binding protein or any fragments thereof.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner, can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



DONNA WORTMAN  
PRIMARY EXAMINER

Robert A. Zeman  
November 29, 2001